

July 7, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Ln, RM 1061
Rockville, Maryland 20857

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To the FDA:

RE: Docket No. 98N-1265

I would like to register my disapproval of the Memorandum of Understanding which was published by the FDA on January 21, 1999.

I use a compounding pharmacy in a state other than my own (I live in Ohio) to fill a hormone prescription which uses naturally occurring hormones as opposed to synthetic ones. It has been a great relief to be free of the side-effects produced by the synthetic hormones. I use Women's International Pharmacy in Wisconsin because of its excellent reputation and because they provide excellent service AND counseling. I want to be free to choose such a pharmacy even if it is NOT in my home state.

I want my right to use such a pharmacy preserved. I want to use the pharmacy of my choice. I do not want to depend on large pharmaceutical companies to meet my medical needs. One of these companies, Solvay Pharmaceuticals, is now producing at least two natural hormones which are competitive with the ones available at the compounding pharmacy. I do not believe this company would have produced the natural hormones if it had not been for the customer demand which was obviously being met by compounding pharmacies.

I also want to preserve the right for me and for my doctor to consult with the pharmacy about alternative options. This is not solicitation. It is dispensing information which I should have the right to hear and they should have the right to dispense. My doctor and I should retain the right to use and communicate with the pharmacy of our choice, even if they specialize in compounded drugs.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer, there should be no restrictions to the delivery of a compounded medication prescribed for me, regardless of where I may live or may travel. The MOU must be amended.

Sincerely,

Mary R. Miller

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98N-1265

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